

1 Heparin Sodium Solution for Dialysis

2 透析用ヘパリンナトリウム液

3

4 Heparin Sodium Solution for Dialysis is a
5 preparation used to prevent coagulation of perfused
6 blood during hemodialysis.

7 It contains not less than 90% and not more than
8 110% of the labeled Heparin Unit.

9 **Method of preparation** Prepare as directed under Injec-
10 tions, with Heparin Sodium.

11 **Description** Heparin Sodium Solution for Dialysis is a
12 clear, colorless to light yellow liquid.

13 Osmotic pressure ratio: 0.9 – 1.1

14 **pH** <2.54> 5.5 – 8.0

15 **Bacterial endotoxins** <4.01> Less than 0.0030 EU/unit.

16 **Extractable volume** <6.05> It meets the requirement.

17 **Foreign insoluble matter** <6.06> Perform the test accord-
18 ing to Method 1: it meets the requirement.

19 **Insoluble particulate matter** <6.07> It meets the require-
20 ment.

21 **Sterility** <4.06> Perform the test according to the Mem-
22 brane filtration method: it meets the requirement.

23 **Assay** Proceed as directed in the Assay under Heparin So-
24 dium, replacing (vii) Heparin sample solutions and (ix) Cal-
25 culations with the following.

26 (vii) Heparin sample solutions: Pipet a suitable volume
27 of Heparin Sodium Solution for Dialysis, dilute exactly
28 with the buffer solution so that each mL contains 0.1 Heparin
29 Units, and use this solution as the sample solution. Pre-
30 pare heparin sample solutions T₁, T₂, T₃ and T₄ respectively
31 by adding the sample solution to the buffer solution as di-
32 rected in the following table.
33

Heparin sample solution		Buffer solution (μL)	Sample solution (μL)
No.	Heparin concentration (Unit/mL)		
T ₁	0.005	950	50
T ₂	0.010	900	100
T ₃	0.015	850	150
T ₄	0.020	800	200

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35 (ix) Calculations: When the regression expression, $y =$
36 $I_c + A_{x_s} + B_{x_t}$, is obtained using y as log of the absorb-
37 ance values, x_s as the concentration of the heparin standard
38 solutions and x_t as the concentration of the heparin sample
39 solutions, the potency ratio R is B/A .

40 I_c : Common intercept

41 A : Slope of regression expression of the heparin standard
42 solution

43 B : Slope of regression expression of the heparin sample
44 solution

45 Calculate Heparin Units (anti-factor IIa activity) in 1 mL
46 of Heparin Sodium Solution for Dialysis by the following
47 formula.

48 Heparin Units (anti-factor IIa activity) in 1 mL of Heparin
49 Sodium Solution for Dialysis
50 $= 0.1 \times R \times V/a$

51 V : Total volume (mL) of the sample solution prepared as
52 containing 0.1 Heparin Units (anti-factor IIa activity)
53 per mL

54 a : Amount (mL) of Heparin Sodium Solution for Dialysis
55 taken

56 However, when a 90% confidence interval of D of the
57 regression expression $y = I'_c + A'_{x_s} + B'_{x_t} + D$, where
58 D is a constant term showing the difference between the in-
59 tercepts assumed from the measurement of the blank and
60 the two lines, is not in the range of between -0.2 and 0.2 ,
61 analyze by excluding the measurements of the blank.

62 The criteria for the test suitability are followed as di-
63 rected in the Assay under Heparin Sodium. When these cri-
64 teria are not satisfied, repeat the test after changing the di-
65 lution rate so that the potency ratio becomes about 1 using
66 the obtained potency as reference.

67 **Containers and storage** Containers—Hermetic contain-
68 ers. Plastic containers for aqueous injections may be used.